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The importance of and current trends in the endovascular program – A single center experience

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ABSTRACT

Introduction: Open vascular surgery and endovascular (EV) interventions are continually developing and their application differs depending on the arterial regions treated. We aim to demonstrate that current EV procedures do not mean a restriction, but on the contrary, an increase in the number of patients who can be successfully treated.

Methods: We have retrospectively followed all open surgery procedures and endovascular interventions done for carotid artery stenosis and subrenal abdominal aortic aneurysms (AAA) from 1990/1993 to 2014 in the Vascular Surgery Department at Na Homolce Hospital.

Results: From 1990 to 2014, 1659 open AAA surgery procedures were done in our department. Since 1996, 1023 endovascular abdominal aortic aneurysm repairs (EVAR) have been performed and since the implementation of robotics, 64 aneurysm replacements were robot-assisted. Mortality rates in the OS, EVAR and robotic groups are 1.7%, 1.5% and 0.4%, respectively. The percentage of EVAR stabilized during the last 5 years at about 32% of the total number of treated patients. From 1993 to 2014 there were 5363 open carotid surgery procedures done in our department, 2856 for symptomatic and 2507 for asymptomatic stenosis. The total cohort combined stroke/death rate was 1.6%. Symptomatic, asymptomatic and urgently operated patients had a combined 30-day stroke/death rate of 1.0%, 1.7% and 4.4%, respectively. During the same period 274 carotid bifurcation and 55 common carotid artery percutaneous transluminal angioplasty (PTA) were done. The technical success of endovascular interventions was better than 95%.

Conclusion: In the AAA group, the percentage of EVAR stabilized during the last 5 years at about 32% of the total number of treated patients. Given the excellent results of open carotid surgery and the unconvincing results of stenting trials, we consider open carotid surgery to be better than carotid artery primary stenting.

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Introduction

The history of open vascular surgery is relatively long in comparison with endovascular interventions. Vascular suture was first used in the 16th century and vascular anastomosis suture was developed during the second half of the 20th century, but the greatest increase in vascular surgery procedures came after 1955 with the commercial production of artificial vascular prostheses (Dubost, Cooley and DeBakey) [1].

The history of endovascular interventions is much shorter but also more rapid. Atraumatic percutaneous access was first described in 1953 (Seldinger) and angioplasty with a conical catheter and later with the angioplasty balloon were first performed in the sixties [2]. Angioplasty was quickly combined with metallic stents. Volodos (1986) and Parodi (1990) improved the procedure of endovascular aneurysm therapy using covered stents, termed stent grafts (SG). Each of these methods, i.e. angioplasty, stenting and stent grafting have undergone rapid and continuous development, and their application differs depending on the arterial regions.

The increased numbers of endovascular (EV) procedures are often a reflection of the hope shown by physicians and patients. Nevertheless, modern methods do not generally demonstrate better clinical results, at least not in all situations, and under certain conditions EV procedures are not seen as a viable life-long solution.

On the evidence from a single center and using the example of two types of vascular impairments we will demonstrate that current EV procedures do not mean a restriction, but on the contrary an increase, in the number of patients who can be successfully treated.

Methods

We have retrospectively followed all open surgery (OS) and EV interventions done for carotid artery stenosis and subrenal abdominal aortic aneurysms (AAA) from 1990/1993 to 2014 in the Vascular Surgery Department at Na Homolce Hospital. These two vascular impairments were chosen because they represent a significant number of open vascular and endovascular surgery procedures. A number of studies comparing the OS and EV approaches to the abdominal aorta and carotid bifurcation have been published during recent years.

Abdominal aortic aneurysm

In general, patients indicated to treatment are either asymptomatic with AAA transverse diameter ≥55 mm, symptomatic with any aneurysm diameter or those with a rapid increase of aneurysm diameter over 5 mm per year [3].

Open AAA surgery has been successfully performed since the sixties and in many centers it is the treatment method of 1st choice. Vascular prostheses have not substantially changed during the last 30 years. Open surgical procedures and their results are historically proven and well documented [4].

A 25-year history of endovascular aneurysm repair with stent graft (EVAR) has brought improvement in core stent technology, prosthetic covering material, introducer sheaths and, in the last generation, a portfolio of fenestrated and branched components. According to manufacturers' instructions for use, the required length for sealing in the proximal neck ranges from 15 to 20 mm, but sometimes stent grafts are used even in shorter necks of 7.5 to 10 mm in length. Fenestrated off-the-shelf stent grafts, available in recent years, enable the treatment of juxtarenal aneurysms and aneurysms of the visceral segment without the significant delay caused by customized manufacturing. In our center, the majority of SG implantations are done in selected asymptomatic or symptomatic patients with moderate or high risk (GAS score >90 or NYHA class III–IV).

Endovascular sealing (EVAS) is a new concept in the treatment of aortic aneurysms [5]. The system consists of two PTFE-covered stent grafts of standard 10 mm diameter surrounded with large bags. They are inserted into the aneurysm. After appropriate SG positioning, both the endobags are filled with biostable polymer, sealing completely the aneurysm sack, the origins of the inferior mesenteric artery, all the lumbar arteries and also the proximal neck in the subrenal portion and distal ends in both common iliac arteries. We treated two patients with this system in 2014 (Fig. 1a and b). Endovascular sealing is indicated for patients with irregular and conical necks unsuitable for standard SG. Another advantage of aneurysm sack sealing is the prevention of all types of endoleak.

Since 2006 we have been able to select anatomically suitable patients for robot-assisted laparoscopic surgery. The introduction of robotics marked a fundamental turning point for laparoscopic vascular surgery, which had always entailed relatively difficult manipulation with instruments and required a long time to construct the vascular anastomosis, leading to long aortal clamping times. The robotic system removes these fundamental disadvantages of laparoscopy and opens up the possibility of expanding robot-assisted laparoscopic surgery in this area.

Robotic technology has been applied in a range of vascular reconstructions of the pelvic arteries, visceral arteries and abdominal aorta. This has ranked the hospital alongside a small number of centers worldwide – able to be counted on the fingers of one hand – where robotic-assisted vascular reconstructions are routinely performed. The experience in the field of vascular surgery allows us to claim that vascular anastomosis can be performed robotically both on the aorta and the pelvic artery with good results and, in fact, more easily than with classical laparoscopic surgery. Robotic vascular procedures can be categorized by surgical site into interventions in the pelvic region, aortic interventions, visceral arteries interventions, thoracic aortic interventions and hybrid procedures.

Compared with open surgery, the robotic system results in a shortened ICU stay, decreased post-surgery pain and accelerated rehabilitation.

Results

Our center gradually introduced all types of AAA treatment. The proportion and number of interventions over consecutive years are depicted in Fig. 2. From 1990 to 2014, 1659 open AAA

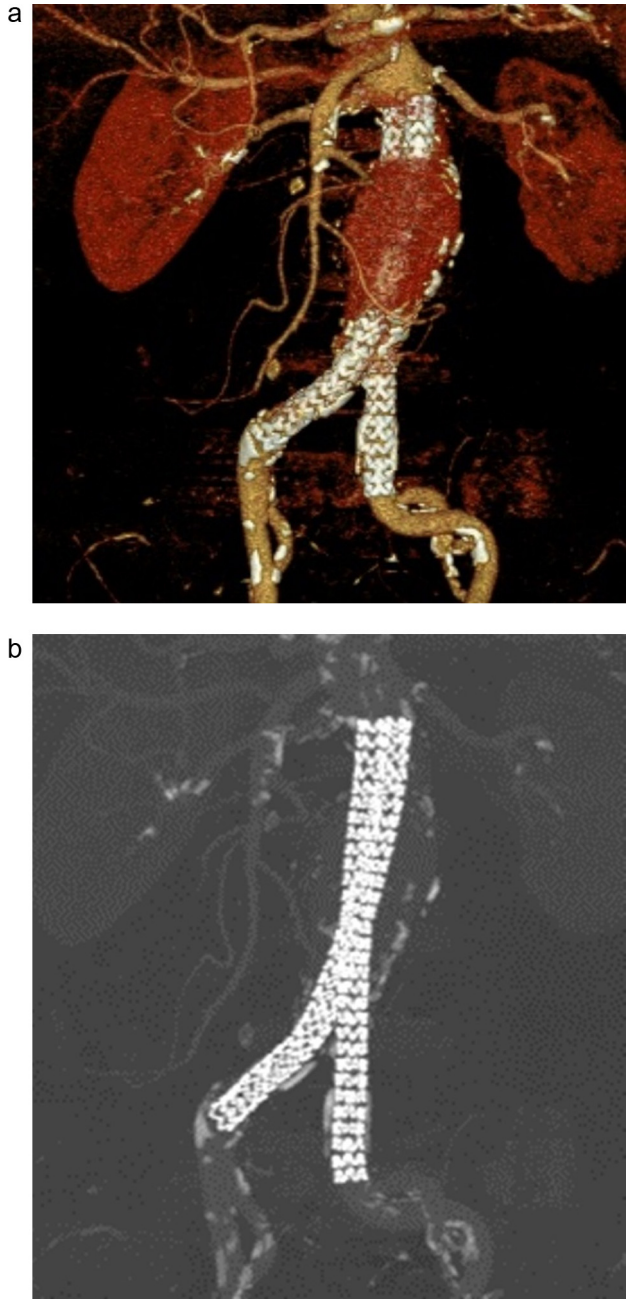

Fig. 1 – CT angiography after application of EVAS, Nellix system (Endologix, CA, USA). Polymer filled endobags follow the inner contours of the aneurysm sack.

surgery procedures were done in our department. Since the introduction of the endovascular program in 1996, 1023 EVAR have been performed. During the ten years since the implementation of robotics, 64 aneurysm replacements were robot assisted. In that period, mortality rates in the OS, EVAR and robotic groups are 1.7%, 1.5% and 0.4% respectively.

The introduction of endovascular and robotic assisted procedures has not caused a decrease in the volume of OS procedures, but, on the contrary, has increased chances of treating those patients for whom the risk with the classical procedure is high. The endovascular approach is also advantageous for patients in the reoperation group. It is possible to avoid repeated laparotomy and the SG can be anchored in the already present vascular prosthesis.

The percentage of EVAR stabilized during the last five years at about 32% of the total number of treated patients. Over the years, the use of various SG types has also varied due to technical improvements and physician experience (Fig. 3). Originally only tubular stent grafts were on the market, but only a few patients were anatomically suitable for tubular SG in the abdominal position, and very often, distal endoleak type I occurred.

Carotid artery bifurcation stenosis

Open endarterectomy of carotid artery (CA) bifurcation was performed for the first time more than 60 years ago. The indication criteria have changed during the last ten years: symptomatic stenosis ≧50% should be treated as soon as possible after the first transitory ischemic attack (TIA) or stroke, provided that the ischemic lesion is smaller than 1/3 of the area supplied by a. cerebri media. The ideal timing for procedure is up to 48 h, and no longer than 14 days after the first embolization episode. In asymptomatic lesions ≧70%, best medical therapy (BMT) is recommended initially, and intervention should be offered to patients with frequent microemboli on trans-cranial Doppler, with echolucent and progressing plaques [6–8].

Open endarterectomy should be performed at specialized vascular centers with a combined number of stroke/perioperative death of <2% [9]. The rate of restenosis is about 4% [10]. The average ICU stay is 6 h and the length of hospital stay (LOS) is typically about 4 days. A large number of open procedures (>25/year) done by a single surgeon is the most important factor for sustained and durable results. The specific surgery technique (eversion versus longitudinal incision) does not significantly influence the long-term results, but generous usage of patch plasty decreases the amount of restenosis and combined perioperative and long-term stroke risk [10,11]. Specialized centers have an average stroke/death rate of 1.5–2% in cohorts of both symptomatic and asymptomatic patients [12]. Thus, open carotid endarterectomy remains standard care for patients with carotid artery stenosis [13].

In a significant number of patients it is not possible to perform an open procedure due to various objective or subjective reasons. The most frequent indications for EV procedure are listed in Table 1. The general criteria for EV procedure are the same as for OS. However, EV procedure also has its contraindications: fresh adhering thrombus, filiform (>95%) or long (>2 cm) stenosis, severe artery tortuosity/kinking, neighboring aneurysmal dilatation or severe allergic reaction to contrast media. The ICU stay is also about 6 h on average and the length of stay is typically about 24 h.

The most serious complication of the EV approach is embolic stroke. The number of severe strokes is significantly reduced with the use of protection tools, but the incidence of subclinical microembolizations is probably higher. Carotid endarterectomy versus carotid stenting randomized trials

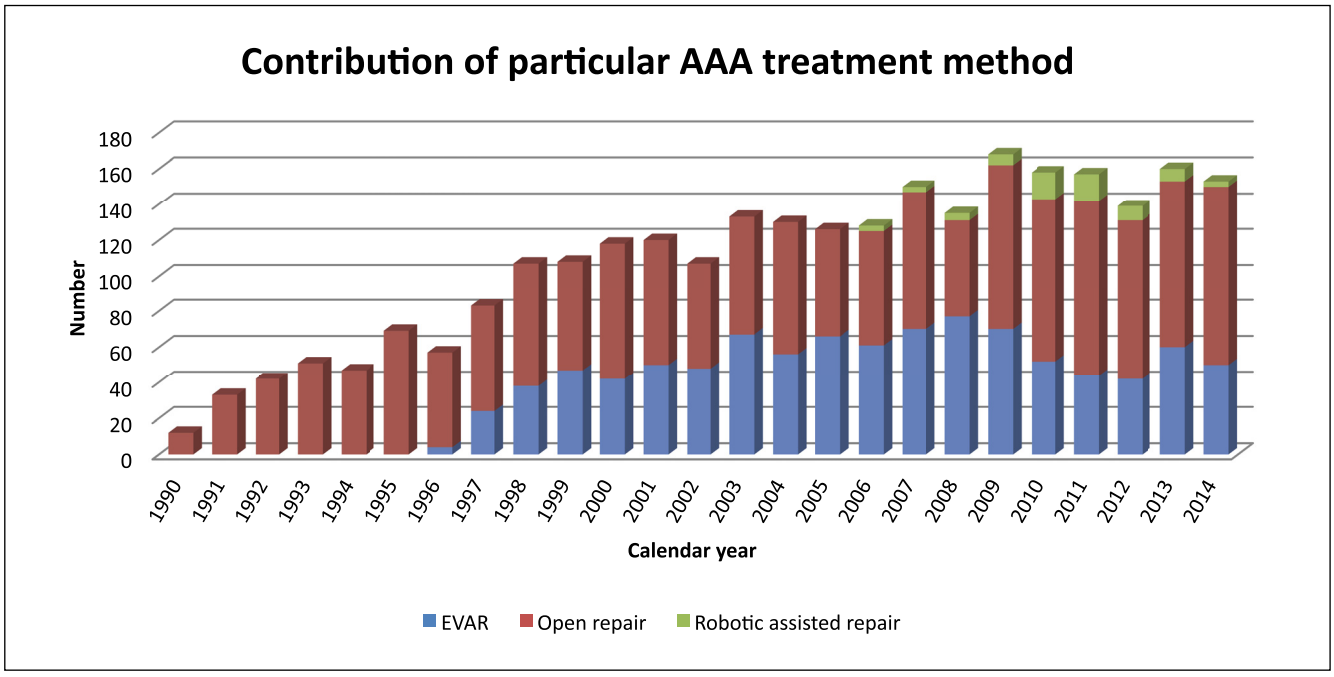

Fig. 2 – Proportion of interventional methods over consecutive years.

have repeatedly proved that stenting causes about twice as many strokes and deaths and more periprocedural deaths or myocardial infarctions or strokes compared with surgery, partly due to inadequate experience among endovascular teams and the non-compulsory use of protective instruments [14–18]. Despite that, many vascular societies in the recent intervention guidelines have adopted new positive recommendations for carotid artery stenting (CAS) for both asymptomatic and symptomatic stenosis. In-stent restenosis and stent thrombosis are late complications with a rate from 3 to 6% after 3 years [19].

Results

In our center, patients are normally offered open endarterectomy. Endovascular procedures are therefore indicated only under the conditions listed in Table 1. Thus, open surgery and EV cohorts are not comparable.

From 1993 to 2014 there were 5363 open carotid surgery procedures done in our department, 2856 for symptomatic and 2507 for asymptomatic stenoses. The total cohort combined stroke/death rate was 1.6%. Symptomatic, asymptomatic

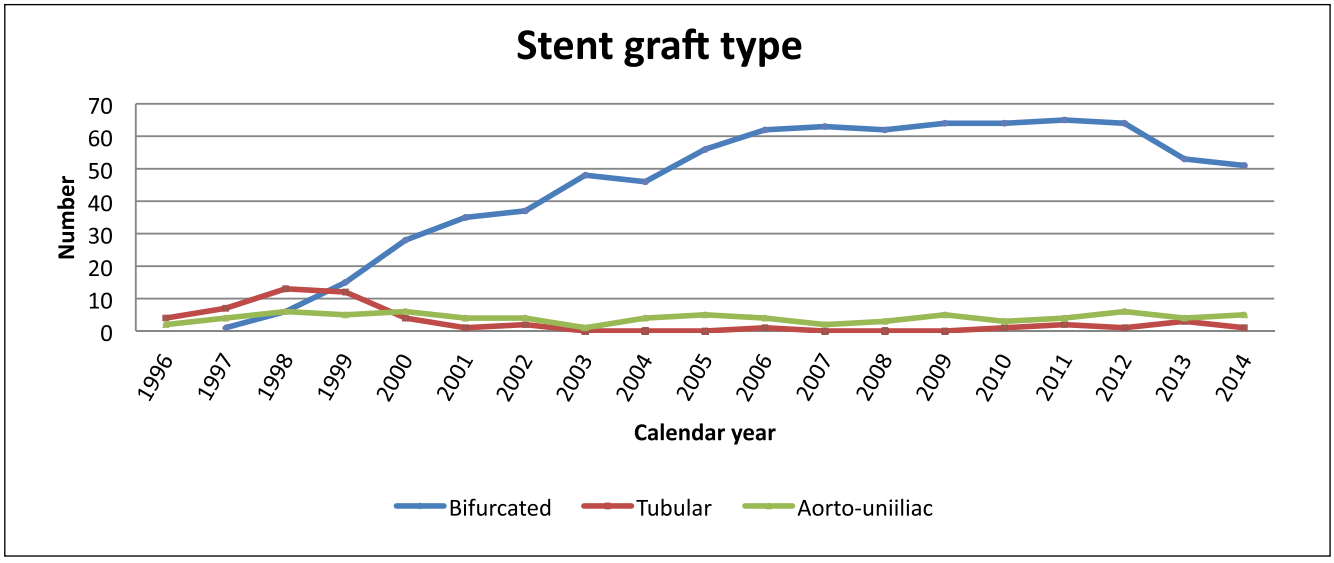

Fig. 3 – Evolution of stent graft types and their use over consecutive years.

Table 1 – Indication for endovascular treatment for carotid artery bifurcation stenosis.

	Indication
1	Early post-endarterectomy restenosis (up to 24 months, method of the first choice)
2	Persons with high risk of perioperative acute myocardial infarction, or persons with indication for contemporary coronary and carotid EV procedure
3	Persons with a history of congestive heart failure
4	Hostile terrain, large scarring, a history of irradiation or regional ENT surgery
5	Non-accessible lesions close to cranial base or low on the common carotid artery, below the clavicle
6	A lesion of the contralateral n. laryngeus recurrens, n. pharyngicus
7	Severe chronic respiratory or renal failure
8	Patient preference

and urgently operated patients had a combined 30-day stroke/death rate of 1.0%, 1.7% and 4.4%, respectively. Cervical nerve lesions occurred in 11% of cases. Post-operative hemorrhage was recorded in 1.1% of procedures. During the same period 274 carotid bifurcation and 55 common carotid artery percutaneous transluminal angioplasty (PTA) were done. While PTA was seldom indicated as a first procedure for carotid stenosis, in the great majority of cases patients with restenosis after primary surgery were indicated for PTA. Technical success was better than 95%. The proportion and number of interventions over consecutive years are depicted in Fig. 4. Given the excellent results of open surgery and the unconvincing results of stenting trials, we consider open carotid surgery to be better than carotid artery primary stenting.

Discussion

We have selected carotid and AAA interventions, two major topics in the field of vascular surgery, as the subject of our study, as they represent a significant proportion of the procedures performed in the Vascular Surgery Department at Na Homolce Hospital. We aim to document that the movement toward more EV interventions is not straightforward as often they do not provide a complete solution. Physicians have to manage not only technical and anatomical problems, but also important ethical, logistical and personal issues, leaving aside the question of health finance.

For AAA, the original and still valid indication for EVAR is the elective treatment of patients for whom surgery is very risky. In a meta-analysis of 21,178 patients who underwent either EVAR or OS for elective AAA repair, EVAR was associated with shorter intensive care unit/total hospital stay, fewer cardiac and respiratory complications and lower mortality rates [20]. However, practise has overtaken theory and shown another possibility – the use of SG in ruptured aneurysms. EVAR in emergent setting has a significantly lower risk of 30 day mortality [21–23]. Ruptured aneurysms need to be treated in the hybrid operating room but under these conditions SG implantation is advantageous as it is performed under local anesthesia, more quickly and with lower invasivity than OS.

The continued development of fenestrated and branched stent grafts may be questionable, as due to the larger introducer sheath, an extraperitoneal approach and construction of the common iliac artery prosthetical conduit will be necessary for access, thus decreasing the advantage of its lower invasivity [24]. In addition, a significant number of patients with branched stent grafts suffer from some endoleak [25]. Abdominal aortic interventions should be performed only at centers with excellent interdisciplinary collaboration between vascular surgeons, interventional radiologists and anesthetists.

There is a further risk: between 2000 and 2011 EVAR procedures in the USA increased from 2358 to 35,028 and, in the same period, OS procedures decreased from 42,872 to 10,039. University centers now indicate so few open procedures that the number does not cover the demand of the young physician education program. Inadequately trained physicians have to deal with complicated cases, as the more simple ones are treated by EVAR [26,27]. In our region there is the opposite risk: trained endovascular specialists are unavailable outside normal working hours and the outdated

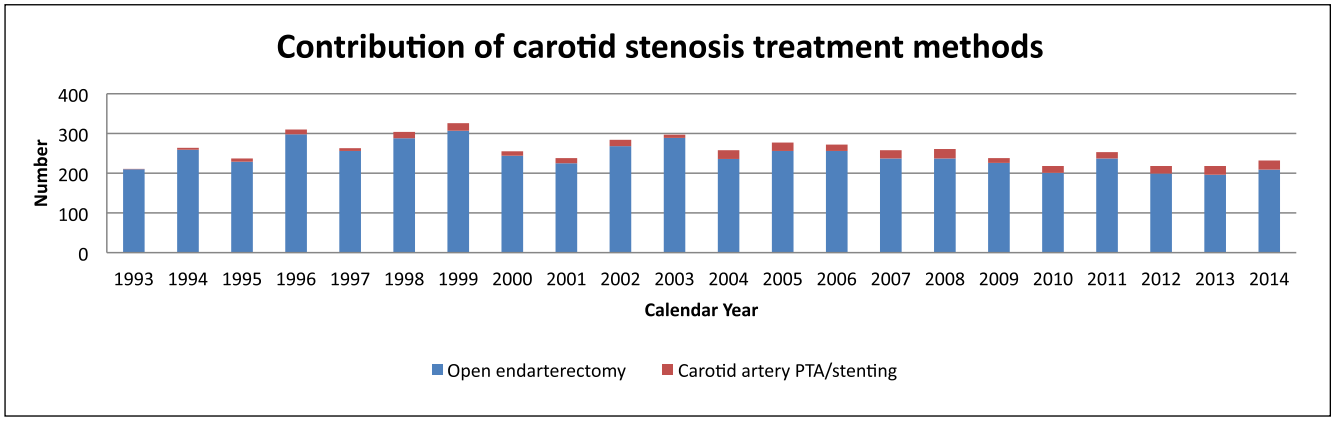

Fig. 4 – Contribution of carotid stenosis treatment methods. Proportion of endovascular procedures ranges from 3 to 11%/year. Impact of the new guidelines caused a decrease in the number of indicated asymptomatic patients and a consequent decrease in the total number of open procedures.

technical equipment necessitates OS treatment for nearly all ruptured aneurysms, with a typical mortality rate of 40–50%.

The results of the EVAR I trial were published in 2010. One of the conclusions was that in the long term no difference was seen in total mortality or aneurysm-related mortality [28]. This has resulted in reduced enthusiasm for elective EV treatment and in a decrease in the total number of EVAR during the last 5 years in our center.

Carotid artery stenting (CAS) has experienced increased popularity during the last decade. However, the data from international studies has failed to persuade many experts that the method is equally effective. Restenosis is more frequent after carotid stenting than after endarterectomy [29]. There is a 20% higher risk of silent brain infarction after stenting, although without measurable change in cognitive functions [30]. Recommendations to give preference to CAS rather than to open endarterectomy should be accepted with caution, as they often reflect a desire rather than the reality [31,32].

Specialized centers have adapted to changes in the discipline and adopted endovascular methods in their portfolia. Occasional voices are still heard predicting that endovascular procedures will completely replace open vascular surgery, which as a speciality will decline. The experience in our center, the Vascular Surgery Department of Na Homolce Hospital, similarly to many other European centers, confirms that vascular surgeons are having to take on the more comprehensive role of vascular specialists. This physician will identify potential patients and be able to investigate them using sonography, angiography or other methods developed in the future. The specialist will then choose and apply the appropriate treatment method alone. The current board education for vascular specialist should move toward reflecting this approach.

Conflict of interest

All authors declare that there is no conflict of interest and there was no outside support funding.

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Ethical statement

All authors declare that the research published in this manuscript was done according to ethical standards.

Informed consent

All authors declare the patients signed informed consents before all the procedures which were retrospectively followed in this manuscript.

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